REMARKS

In the Office Action, the Examiner rejected claims 29-39 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement and the enablement requirement. The Examiner rejected claims 29-39 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Examiner rejected claims 36-39 under 35 U.S.C. §102(e) as being anticipated by U.S. Patent 6,838,259 issued to Suenaga et al. ("Suenaga"). The Examiner rejected claims 29 and 31-35 under 35 U.S.C. §102(a) as being anticipated by Non-Patent Literature titled "The GPR54 Gene as a Regulator of Puberty" written by Seminara et al ("Seminara").

In this Amendment, Applicants have amended claims 29-39. Applicants have added claims 40-52. Applicants do not surrender any equivalents to any amended elements or limitations of any amended claim. Applicants also assert a right to any equivalents of any elements in any new claim, regardless of any overlap between the elements of any new claim and any pre-or-post amendment elements of any amended claim. Accordingly, claims 29-52 will be pending after entry of this Amendment.

I. Rejection of Claims 29-39 Under 35 U.S.C. §112, First Paragraph – Written Description

In the Office Action, the Examiner rejected claims 29-39 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner stated that no basis of the claims was provided in the specification.

Applicants respectfully disagree and traverse the rejection to claims 29-39 for at least the following reasons. Applicants respectfully submit that the specification does indeed provide a basis for the claims. More specifically, the specification teaches a composition comprising GnRH and at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1

peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins. *See, e.g.,* Specification, page 5, line 33-38, and page 17, line 14, through page 18, line 31. Additionally, Applicants respectfully submit that the specification teaches a method for treatment of a gonadotropin related disorder comprising administration of said composition. *See, e.g.,* Specification, page 1, line 5-10, and page 17, line 14, through page 18, line 31. Furthermore, Applicants respectfully submit that the specification teaches a method for treatment of stimulation of ovulation comprising administration of said composition. *See, e.g.,* Specification, page 5, line 21-23, and page 17, line 14, through page 18, line 31.

Accordingly, Applicants respectfully submit that each claim and every term used in claims 29-39 is fully supported in the specification. Applicants respectfully submit that claims 29-39 are in condition for allowance. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §112, first paragraph rejection of claims 29-39.

II. Rejection of Claims 29-39 Under 35 U.S.C. §112, First Paragraph - Enablement

In the Office Action, the Examiner rejected claims 29-39 under 35 U.S.C. §112, first paragraph, as failing to comply with the enablement requirement. Specifically, the Examiner states that the specification does not enable production of the claimed compositions nor how to use the claimed compositions.

Applicants respectfully disagree and traverse the rejection to claims 29-39 for at least the following reasons. *First*, Applicants respectfully disagree and traverse the objection regarding that the peptides claimed are not described in accordance with the written description requirement. The written description requirement of 35 U.S.C. 112 does not require that all possible embodiments be expressly described in terms of sequence or structure in order to show possession. In Enzo Biochem vs. Gen-probe Incorporated 296 F.3d 1316, sequences which were not sequenced or disclosed were claimed in accordance with 35 U.S.C. 112 because they were

obtainable by a one of ordinary skill in the art and thus were enabled. In Moba vs. Diamond Automation 325 F.3d 1306, it was ruled that the language of 35 U.S.C. 112 indicates that a patent will contain an adequate description if it provides enough information to enable one of ordinary skill in the art to make and use the invention.

Any disclosure that enables one to make and use the invention, by definition, also shows that the inventor was in possession of that full invention. After all, to enable is to show possession, and to show possession is to enable. Clearly, judicial opinion is adverse to a rule according to which all sequences must be disclosed in order to be validly claimed especially when they are properly enabled. As Judge Rader pointed out in the Moba case, having to disclose all sequences in order to validly claim these sequences even though these sequences are enabled is impracticable. Furthermore, it is not necessary to incorporate by reference in order to use elements well-known in the prior art. Thus, it is permissible for Applicants to refer in a claim to a compound which has a defined meaning in the art.

Patent application WO/03003983 published on January 16, 2003, which is prior to the priority date for the present application, discloses Kiss-1 peptides. Similarly, Kisspeptin and Kiss-1 proteins are discussed and disclosed in the publications of Katani, et al. and Otaki, et al. Similarly, EP1126028, published on August 22, 2001, discloses these proteins further. As such, the proteins claimed are well known in the art as of the priority date. The full sequence of the claimed proteins can also be found in the part of the prior art which the specification specifically points to. Therefore, Applicants respectfully submit the specification is in compliance with the ruling of the Moba vs. Diamond Automation case and that the claimed sequences can be obtained by one of ordinary skill in the art.

Second, the objection based on the experiment described in the specification is traversed on the grounds that the issue is whether the invention can be reproduced. It is not necessary for

the Applicants to demonstrate the claimed use. Contrary to the Office Action's contentions, the specification does enable the production of the claimed composition and the claimed use. Unless the Office Action can provide evidence that the claimed method would not work, it is not permitted to base a rejection on mere doubt about the reasoning of the Applicant. An examination of the USPTO revised guidelines shows that what is required is a credible utility and not absolute scientific certainty. It is further stated in the MPEP section 2107.02 (III)B that:

> "Where an Applicant has *specifically asserted* that an invention has a particular utility, that assertion *cannot simply be dismissed by Office personnel as being 'wrong'* ... Rather, Office personnel must determine if the assertion of utility is credible (i.e., whether the assertion of utility is believable to a person of ordinary skill in the art based on the totality of evidence and reasoning provided). An assertion is *credible unless* (A) the *logic* underlying the assertion is *seriously flawed*, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion." (emphasis added)

Applicants respectfully submit the Office Action does not provide evidence that the claimed compositions cannot be synthesized and that the composition cannot be used as described. Furthermore, Applicants have specifically asserted the logic that the composition has the effects stated in the specification. This logic is not flawed and the experiment cited in the specification is consistent with this logic.

Accordingly, Applicants respectfully submit that claims 29-39 are in condition for allowance. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §112, second paragraph rejection of claims 29-39.

III. Rejection of Claims 32-35 Under 35 U.S.C. §112, Second Paragraph

In the Office Action, the Examiner rejected claims 32-35 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have amended claims 32-35 to be method claims. Applicants respectfully submit that the claims as amended particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, Applicants respectfully submit that a claimed use in a method claim is a valid limitation.

Accordingly, Applicants respectfully submit that claims 32-35 are in condition for allowance. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §112, second paragraph rejection of claims 32-35.

IV. Rejection of Claims 37-39 Under 35 U.S.C. §112, Second Paragraph

In the Office Action, the Examiner rejected claims 37-39 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to point out and distinctly claim the subject matter which Applicants regard as the invention.

Applicants have amended claims 37-39 to be method claims. Applicants respectfully submit that the claims as amended particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, Applicants respectfully submit that a claimed use in a method claim is a valid limitation.

Accordingly, Applicants respectfully submit that claims 37-39 are in condition for allowance. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §112, second paragraph rejection of claims 37-39.

V. Rejection of Claims 36-39 under 35 U.S.C. §102(e)

In the Office Action, the Examiner rejected claims 36-39 under 35 U.S.C. §102(e) as being anticipated by Suenaga. Claims 37-39 are dependent on claim 36.

Claim 36 recites a method for stimulation of ovulation. The method includes the administration of a composition. The composition includes GnRH. The composition includes at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins. Applicants have amended claims 36-39 to be method claims. Applicants respectfully submit that the claimed use in the claims as amended is a valid limitation.

Furthermore, Applicants respectfully submit that Suenaga does not anticipate claim 36 for at least the following reasons. Applicants respectfully submit that Suenaga does not disclose, teach, or even suggest a method for using Kiss-1 peptides. Suenaga only teaches the process of producing Kiss-1 peptides without teaching what the produced Kiss-1 peptides are used for. Thus, Suenaga does not teach a method for using Kiss-1 peptide in combination with GnRH for stimulation of ovulation. In contrast, claim 36 recites a method of using Kiss-1 peptides in combination with GnRH for stimulation of ovulation.

In view of the foregoing remarks, Applicants respectfully submit that Suenaga does not anticipate claims 36-39. Given that claims 37-39 are dependent on claim 36, Applicants respectfully submit that these claims are allowable over the cited reference for at least the same reasons that were provided above for claim 36. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §102(e) rejection of claims 36-39.

VI. Rejection of Claims 29 and 31 under 35 U.S.C. §102(a)

In the Office Action, the Examiner rejected claims 29 and 31 under 35 U.S.C. §102(a) as being anticipated by Seminara. Claim 31 is dependent on claim 29.

Claim 29 recites a composition that includes GnRH. The composition also includes at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins.

Applicants respectfully submit that Seminara does not anticipate claim 29 for at least the following reasons. Applicants respectfully submit that Seminara does not disclose, teach, or even suggest the administration of a composition comprising both GnRH and Kisspeptin-1. Figure 3 of Seminara is the result of an in-vitro test (see page 1619 column 2 paragraph 1) in which cells were transfected with a construct and then challenged with Kisspeptin-1. GnRH was not given to these cells. On the other hand, Figure 6 of Seminara discloses that some of the mice had received GnRH, but does not disclose the use of Kisspeptin-1. In fact, there is no indication anywhere in this article that mice would have been challenged with both GnRH and Kisspeptin-1. Furthermore, Applicants respectfully submit that the current set of claims cannot be construed as claiming a living animal that would contain within itself both of these compounds (GnRH and at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins). Applicants respectfully submit that it is absurd to argue that a living animal containing both of these compounds invalidates the claimed composition that comprises both of these compounds. Thus, Seminara does not teach the administration of a composition comprising both GnRH and Kisspeptin-1.

In view of the foregoing remarks, Applicants respectfully submit that Seminara does not anticipate claim 29. Given that claim 31 is dependent on claim 29, Applicants respectfully submit that the claim is allowable over the cited reference for at least the same reasons that were provided above for claim 29. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §102(a) rejection of claims 29 and 31.

VII. Rejection of Claims 32-35 under 35 U.S.C. §102(a)

In the Office Action, the Examiner rejected claims 32-35 under 35 U.S.C. §102(a) as being anticipated by Seminara. Claims 33-35 are dependent on claim 32.

Claim 32 recites a method for treatment of gonadotropin related disorders. The method includes administration of a composition. The composition includes GnRH. The composition also includes at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins.

Applicants respectfully submit that Seminara does not anticipate claim 32 for at least the following reasons. Applicants respectfully submit that Seminara does not disclose, teach, or even suggest the administration of a composition comprising both GnRH and Kisspeptin-1. Figure 3 of Seminara is the result of an in-vitro test (see page 1619 column 2 paragraph 1) in which cells were transfected with a construct and then challenged with Kisspeptin-1. GnRH was not given to these cells. On the other hand, Figure 6 of Seminara discloses that some of the mice had received GnRH, but does not disclose the use of Kisspeptin-1. In fact, there is no indication anywhere in this article that mice would have been challenged with both GnRH and Kisspeptin-1. Furthermore, Applicants respectfully submit that the current set of claims cannot be construed as claiming a living animal because it would contain within itself both of these compounds (GnRH and at least one of Kiss-1 peptides, Kiss-1 peptide fragments, kisspeptins, salt of Kiss-1 peptides, salt of Kiss-1 peptide fragments, and salt of kisspeptins). Applicants respectfully submit that it is absurd to argue that a living animal containing both of these compounds invalidates the claimed composition that comprises both of these compounds. Thus, Seminara does not teach the administration of a composition comprising both GnRH and Kisspeptin-1.

In view of the foregoing remarks, Applicants respectfully submit that Seminara does not anticipate claim 32. Given that claims 33-35 are dependent on claim 32, Applicants respectfully

submit that the claims are allowable over the cited reference for at least the same reasons that were provided above for claim 32. In view of the foregoing, Applicants respectfully request reconsideration and withdrawal of the §102(a) rejection of claims 32-35.

VIII. New Claims 40-52

In this Amendment, Applicants have added claims 40-52. Applicants respectfully submit that claims 40-52 are fully supported by the specification. Claim 40 is indirectly dependent on claim 36. Claims 41-52 are directly or indirectly dependent on claim 32. As claim 40 is dependent on claim 36, Applicants respectfully submit that claim 40 is patentable for at least the same reasons that were discussed above for claim 36. As claims 41-52 are dependent on claim 32, Applicants respectfully submit that claims 41-52 are patentable for at least the same reasons that were discussed above for claim 32.

CONCLUSION

In view of the foregoing, it is submitted that all pending claims, namely claims 29-52 are in condition for allowance. Reconsideration of the rejection is requested. Allowance is earnestly solicited at the earliest possible date.

Respectfully submitted,

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